Natural Rubber Latex Allergy, An Epidemic in the Health Field

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Abstract:

The object of this paper is to educate health care providers of the markedly increased incidence of natural rubber latex (NRL) allergy to epidemic proportions during the past 10 to 12 years. A review of latex allergy problems in health care providers as well as patients is presented. Also reported is a questionnaire survey of institutions listed with the Health Care Association of Hawaii.

Introduction:

Natural rubber latex proteins are products derived from the milky fluid (latex) commercially produced from the rubber tree, Hevea brasilensis. Synthetic latex, as used in latex paints, does not cause allergic reactions in patients with natural rubber latex allergy. For easier reading, "latex," unless otherwise indicated, will refer only to natural rubber latex in this article.

The incidence of latex allergy has markedly and progressively increased by an estimated 64 fold during the past 10 years. The seriousness of an anaphylactic reaction to latex is compounded by the fact that many items commonly used to treat anaphylaxis may contain latex which if used, violates the primary principal of avoiding further exposure to the allergen inducing the reaction.

This article addresses significant latex allergy problems that affect both patients and health care providers who are affected with latex allergy when they, themselves, need health care. Also reported is a study of a survey of 18 Hawaii hospitals and 4 nursing homes.

Methods:

A cursory review of the literature concentrating on review articles, was done to provide basic information about latex allergy in this article. Questionnaires with a letter of explanation were sent to the Chief Executive Officer or comparable person of 41 member institutions of the Health CareAssociation of Hawaii. The recipient was asked to answer question #1 and refer the other questions to the most appropriate individual in that institution for a response. Twenty-two completed questionnaires were returned. The questions were condensed to the subject addressed in each question and the results are tabulated in table 1.

Table 1

Subject of Question	Yes	No	N/A	Other
1. Aware of latex allergy epidemic	20	1		see text
2. Facility has a latex allergy committee	15	5	1	
3. Has operating room(s) entirely latex free	4	2	9	5 alternatives
4. Latex free patient rooms	15	2	1	2
5. Number of employees at risk of latex allergies	8,301	5,486		see text
6. Known employeess with latex allergies	67			see text
7. How do you address latex sensitive employees				see text
8. Use latex powdered gloves:				
a. in hospital rooms only	4			1 options
b. only with direct contact with patient	13			
c. in all departments	7	6		1 options
9. Factors considered in purchasing latex gloves				
a. least concentration of latex protein	6			
b. less processing chemicals in gloves	13			
c. hypoallergenic gloves		9		1
d. list other factors	13			see text
10. Understanding of hypoallergenic gloves				
a. less latex in gloves	0			
b. less processing chemicals in gloves	6			
c. both of the above	13			2 see text
11. Would you like an education session (latex allergy problems)	10	10		1
12. Would you like additional material regarding subject of latex allery	11	10		

Results:

The yes/no answers are self explanatory with a few exceptions as noted under other "see text".

The one "no" answer on question #1 was from a hospital that is properly addressing latex allergy problems. The "no" response was due to being unaware of the "epidemic" aspect.

Questions #5 & #6: The total number of employees listed by the various hospitals and other facilities responding was 14,238. The number of supportive workers that have direct contact with patients is listed in table 1: Sixty-seven known latex sensitive employees reported in the study is 0.52% of the total number of workers employed. Of this number, 9 were contact allergic dermatitis only.

Question #7: One hospital that is latex-free had no cases. No one was terminated from employment due to latex allergy. One was assigned to another job. Thirteen changed to wearing non-latex

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gloves. Two of these were also assigned to another job.

Question #9d: Other factors listed as significant in determining purchase of latex gloves were availability, various details of contracts, user need, elongation properties, specific objective RAST and LEAP data, powder-free, and characteristics that provide protection required for infection control.

Questions #11 & #12: The author participated in providing a 1 hour education session, using a video tape and slides to discuss latex allergy problems at each of 3 hospitals. Information was sent to all of those requesting additional information in question #12.

Summary:

This study reveals that key personnel from each organization are well aware of the problem of latex allergy being on the increase. While 2/3 of the institutions in this study are appropriately addressing problems with latex allergy, 1/3 need to take significant action. Most of these requested assistance to address their problems. In this survey, the incidence of known latex allergic individuals reported is below that expected for the general population and about 20 times less than expected in health care workers. If cases of latex sensitive workers are missed or not addressed, those sensitized health care workers with continued exposure to latex are likely to become progressively more sensitive and develop a more severe illness. Severe allergic reactions may cause devastating health problems for the sensitized employee including rare cases of inability to perform duties, sometimes in highly specialized jobs, and lead to very costly workers' compensation payments.

Discussion:

Type I, IgE mediated latex allergic reactions may be severe, causing disability or even death. Sensitization results from exposure of susceptible individuals to latex rubber proteins possibly enhanced by presence of endotoxin which may act as an immunologic adjuvant. Presence of these potential allergens varies tremendously among manufacturers and even from batch to batch[1]. Allergic reactions to a wide range of medical products that contain latex have been reported including latex surgical gloves, adhesive bandages, intravenous catheters, and anesthesia equipment. Latex gloves are the largest single source of exposure to these potent allergens[2]. Exposure to a latex allergen may be by direct contact with an offending device[3-4] or by inhalation of allergen carried by the cornstarch powder with which most powdered gloves are coated[5-6].

The clinical manifestations of latex allergy range from classic contact urticaria (Type IV reactions) to contact urticarial syndrome and systemic allergic reactions culminating in anaphylaxis (Type I reactions). Continued exposure to latex in sensitized persons may progress to generalized IgE-dependent allergic responses including generalized urticaria or pruritis, rhinoconjunctivitis, asthma, or anaphylaxis which may present as hypotension, shock, respiratory failure, and may be fatal[7]. Treatment of an anaphylactic reaction may be with items that contain latex materials and further worsen the anaphylactic reaction (see table 2)[8-11].

Latex occupational exposure from powdered gloves, especially in asthmatics, may lead to persistent impairment and, although rarely, prevent a worker from remaining in that environment. The American Academy of Asthma, Allergy and Immunology and the American College of Asthma, Allergy and Immunology boards of directors issued a positional statement concerning the use of powdered and non-powdered natural rubber latex gloves[12]. The following steps should be taken to lessen risk of exposure to latex rubber proteins:Latex gloves should be used only as mandated by accepted Universal Precaution Standards. The routine use of latex gloves by food handlers, housekeeping, and medical personnel in low risk situations (e.g. food handling), bed transport, routine physical examination) should be discouraged. Only low allergen latex gloves should be purchased and used. This may reduce the occurrence of reactions among sensitized personnel and should reduce the rate of sensitization[13-15]. Only powder-free latex gloves should be purchased and used. This will nearly eliminate latex aeroallergen levels and exposure[16-18].

As of September 30, 1998, the Food and Drug Administration (FDA) issued a final rule requiring that all products containing natural rubber latex that contacts humans, state: "Caution, This

Table 2.—Common Medical Devices Containing Latex

USED IN THE HOSPITAL	IN ANESTHESIA EQUIPMENT
Mattresses found on stretchers	Rubber masks
Rubber gloves	Electrode pads, e.g., electrocardiogram, peripheral nerve stimulator
Adhesive tape	Head straps
Urinary catheters	Rubber tourniquets
Electrode pads	Rubber nasal-pharyngeal airways
Wound drains	Teeth protectors
Stomach and intestinal tubes	Bite blocks
Condom urinary collection devices	Blood pressure cuffs (inner bladder and tubing)
Protective sheets	Rubber breathing circuits
Enema tubing kits	Reservoir breathing bags
Dental cofferdams	Rubber ventilator hoses
Rubber pads	Rubber ventilator bellows
Fluid circulating warming blankets	Rubber endotracheal tubes
Hemodialysis equipment	Latex cuffs on plastic tracheal tubes
Ambu bags	Latex injection ports on intravenous tubing
Bulb syringes	Certain epidural catheter injection adapters
Elastic bandages, AceTM wraps	Multidose vial stoppers
Medication vial stoppers	Patient controlled analgesia syringes
Stethoscope tubing	Injection ports on intravenous bags
Band-AidsTM and other similar products	
Gloves - examination and sterile	
Patient controlled analgesia syringes	
Tourniquets	

Product Contains Natural Rubber Latex Which May Cause Allergic Reactions"[19].

The regulations also require the removal of the "hypoallergenic" claim on products that removed certain additives that may cause contact dermatitis, but still contain latex; even if at reduced levels of latex as it is a misleading claim since small amounts of latex can trigger allergic reactions. This change in requirement of labeling should greatly facilitate treatment facilities in identifying latex items.

Bauer et al. demonstrated that those subjects with latex specific IgE antibodies worked in rooms contaminated with latex aeroallergens at levels of 0.6 ng/m^3 or greater. They demonstrated that as long as powdered latex gloves are used in hospitals, latex allergens will be spread into the air of hospital rooms. Latex aeroallergens were present in all rooms without ventilation systems and in 4 of the 16 rooms with ventilation systems and fresh air supply. The concentration of latex aeroallergens ranged from 0.4 to 205 ng/m^3. A relationship was not found between total dust and latex aeroallergens concentration on the basis of an investigation of 30 rooms. One effective measure shown to eliminate or reduce latex sensitization, especially in those health workers already sensitized, is to control the spread of latex aeroallergens in working environments with use of powder-free latex gloves[20].

A brief review of the history of immediate hypersensitivity reactions to latex demonstrates that, indeed, an epidemic of natural latex rubber allergies has occurred during the past 10 to 12 years. The first reported reactions to latex were in Germany, in 1927. The next published case appeared 52 years later. The earliest North American reports were published simultaneously in 1989. Over the next 4 years, the US FDA received over 1,100 reports of injury including 15 children with spina bifida who died due to exposure to latex cuffs on barium enema catheters. These cuffs have since been replaced with silicone. An additional 1,700 reports of severe allergic reactions from latex in medical devices were received in the following 10 years [21].

According to Sullivan, recent estimates place the prevalence of clinically important IgE sensitivity to latex at nearly 1% of the total US population, 5 to 17% of health care workers and as high as 65% of patients with spina bifida. Approximately 2% of the personnel working in general hospitals appear to have asthma caused by inhalation of latex dust and as many as 20% of these health care workers are expected to become too ill to continue to work in their current hospital environment. An estimated prevalence of less than 3% of health care workers in 1987 has increased to exceed 10% in 1995[22]. At another conference, Sullivan presented similar data and points out the magnitude of the problem in tables 3 & 4[23].

Health care workers, children with spina bifida and urogenital abnormalities and workers with unconditional exposures to latex are at high latex sensitivity risk. In addition, atopic individuals are at high risk and in combination with the above increased exposures have a compounded increase risk to develop increased sensitivity to latex. To identify IgE mediated sensitivity one may use skin prick tests or blood tests such as RAST tests to verify the presence of specific IgE antibodies to latex[23].

Patients who have immediate hypersensitivity to latex must be treated in a latex controlled environment. Such an environment would be free of latex gloves in the patient's room and surgical suite. No latex accessories such as listed in table 2[8-11] should come in contact with the patient. Means to prevent non-sensitive individuals from becoming sensitive would be to use latex gloves with negligible allergen content. Powder-free latex gloves and non-latex gloves and other medical items should be purchased to minimize exposure to latex allergens[7].

Patients with a diagnosis of latex allergy by history or skin testing and a history of anaphylaxis to latex, should wear a medical identification bracelet, carry a medical identification card or both. It is important for them to carry epinephrine and antihistamines for self-administration. In addition, they should take non-latex gloves to their dentist and physicians who may need to do examinations using gloves.

In a volunteer study group of 247 nurses who were recruited from the Operating Room Nurses Association of Canada Annual Meeting, all underwent skin prick testing with extracts of five latex gloves. One-hundred-thirty-five (54.7%) described allergic symptoms attributed to latex exposure. Of these only 12 (4.9%) tested positive to latex extracts alone, 12 (4.9%) tested positive to food extracts alone, and 5 (2.0%) tested positive to both latex and cross reacted to foods tested (kiwi, banana, avocado, and potato). Three of the 17 (17.6%) nurses who tested positive to latex had no history of reacting to latex.

Indirect latex ELISA was done on the serum of the skin test positive patients with a 70.6% sensitivity.

Table 3.—Scope of Latex Allergy Epidemic

Estimates of the prevalence of IgE to natural rubber latex antigens in various US populations:

<1% of the general population.

1-6% of allergic rhinitis and asthma patients skin test positive (1% at Emory '94-'99).

6-7% of blood donors RAST positive, 2% strongly positive.

5-17% of RN, MD with frequent glove use.

20-30% of atopic exposed RN,MD.

50% of spina bifida patients.

(6-8% of dentists and dental assistants report latex allergy on questionnaire).

Table 4

	#(1992)	IF % LA**	# WITH LA
*HCW in hospitals	4,848,300	8%	387,864
Ltx asthma in hospitals		2%	96,966
HCW in MD offices	1,472,700	8%	117,816
DDS offices	542,000	8%	43,360
Surgeons	135,000	8%	10,800
Total MD	687,000	8%	54,960
Total US population	255,000,000	0.5%	1,275,000
Medical students	15,554 new at risk/year		
Nursing students	72,230 new at risk/year		

*HCW - Health Care Workers ** LA - Latex Allergy

Fifty-four percent of the participants attributed symptoms to latex exposure. The most common symptom was a rash on the hands, itchiness, and scaling. Eleven of 17 (64.7%) of the nurses testing positive to latex had two or more symptoms referable to either skin with rash or blistering, eyes with ocular swelling, burning or itching, or respiratory with symptoms of cough or wheeze.

Thirty-nine of the 135 (28.8%) reported reactions to latex products other than gloves. A history of atopy was strongly associated with the latex skin prick test positivity. Thirty-five of 230 (15.2%) non-reactors, have a history of atopy compared with 9 out of 17 or 52.9% reactors with a history of atopy. A large number of nurses wearing latex gloves noted irritation of their skin. It should be noted that both delayed hypersensitivity to latex and irritant dermatitis would explain many of these individuals problems.

To date there is no standardized latex solution available for assessing these patients. Testing done in Canada with natural rubber latex allergen provided a positive response in 94% of subjects who also reacted to 1 or more of the glove extracts.

This suggested that prick skin testing with a battery of glove extracts of known protein content may be used for accurate evaluation of natural rubber latex allergies[24].

The clinical history in patients with type 1 IgE mediated latex reactions is often both convincing and compelling. However, it alone is not sufficient to definitively establish a diagnosis of latex allergy.

Hamilton, et al, reports a multicenter latex testing efficacy study using non-ammoniated latex. The extract, processed by Greer Laboratories which was prepared from sap taken directly from the *Hevea brasilensis* tree and serially tested at doses of 1,100, and 1,000 mcgm per ml using a prick puncture technique with bifurcated needles.

The clinical history combined with 1 or 2 stage latex rubber glove provocation assay was used to determine the definitive allergic latex status of 324 subjects enrolled in the study. The diagnostic specificity of the agent was demonstrated to be 100% and the sensitivity was 95% at the 100 mcgm per ml concentration with none of the patients in the non-latex allergic group developing a positive skin test response. At the 1,000 mcgm per ml concentration, the diagnostic sensitivity and specificity were 99% and 96% respectively.

The report of this study is promising and hopefully latex skin testing material will soon become available to assist in a definitive diagnosis. A definitive diagnosis is particularly important as it relates to social, occupational, and other legal ramifications of the condition[25].

Conclusion:

In conclusion, natural rubber latex allergy has increased tremendously during the last 10 to 12 years. The most common exposure in health care workers is to latex gloves. Powdered latex gloves creates a significant environmental problem in acting as a vehicle to allow the latex proteins to be airborne. The use of powdered latex gloves should be discontinued in all health care facilities including physicians offices, hospitals, and other health care facilities. Anaphylactic reactions to latex proteins are especially serious and compounded if an anaphylactic reaction is inadvertently treated with devices containing latex. Latex contact to mucosal or serosal surfaces may produce anaphylaxis in sensitive persons who only develop dermatitis with skin contact.

Latex allergy diagnosis is made by taking an appropriate history to establish atopy in the patient and/or allergic type reactions when the person is exposed to latex products. RAST or similar tests may be of value, but are not definitive to establish the diagnosis. Hopefully, standardized skin test materials will be available soon. Prevention is to minimize exposure and to decrease the risk of sensitization by purchasing non-latex products or latex products with a low content of latex and minimal endotoxin contaminant. Treatment of the sensitized patient is by avoidance of exposure and symptomatically if exposed. Labeling latex products and appropriately excluding the misleading term "hypoallergenic" from labels on latex products dispensed after September 30, 1998 will assist in more appropriate purchase of products and implement improvement of manufacturers standards. The study reported in this article indicates that continued education of health care workers in Hawaii regarding the subject of latex allergy must be pursued.

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